GMP grade embryonic stem cell lines approved by NIH

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The NIH has approved four new human embryonic stem cell lines for federally funded research. The lines, from CIRM-funded BioTime, have one thing going for them that many other lines don't. They were developed in compliance with Good Manufacturing Practice requirements, which is a critical step for developing a transplantation therapy. The FDA will only allow clinical trials involving cells and materials that were developed according to GMP guidelines, which carefully control the quality and consistency of a product. Working with cells that are already GMP-compliant removes that time-consuming step from the process of submitting a new clinical trial to the FDA.

Medical News Today quotes BioTime President and CEO, Michael West:

> "This approval is key to our strategy of making our bank of GMP-compliant hES cell lines the industry standard for the development of a wide array of new human therapeutic products. We believe our ESI hES cell lines are the best characterized and documented lines available today. Our clinical grade hES cell lines were derived using procedures and documentation that are in compliance with current Good Tissue Practices (cGTP) and cGMP, which we believe will facilitate the transition of therapeutic products derived by researchers from these cell lines from laboratory to clinical use. We're grateful the NIH has approved the use of ESI-014 and ESI-017 and we look forward to working with researchers to translate the science into commercially successful therapeutic products."

In December 2010 BioTime agreed to make research grade versions of their embryonic stem cell lines available to CIRM researchers. According to a BioTime press release those have been supplied to dozens of researchers throughout California.

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